

Remarks

Claims 1-39 are pending in the application, with claims 1, 25, 31, and 33-39 being the independent claims. Claims 25 and 31 are canceled. Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejections.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-22, 24, 26-30, and 32-39 were rejected under 35 U.S.C. 103(a) as being unpatentable over Blevins (WO 98/26872) in view of Novotny, et al. (5,453,382), and certain Stratagene and GIBCO advertisements. Applicants respectfully traverse.

1. The Blevins and Novotny references are not analogous to the claimed invention.

To be properly relied upon as reference under 35 U.S.C. § 103, a reference must be analogous to the claimed invention. See MPEP 2141.01(a). "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992).

The claims recite methods and devices for extracting nucleic acids from a mixture. Blevins and Novotny do not disclose methods for extracting nucleic acids. Rather, these references demonstrate the separation of non-analogous small molecule analytes (e.g., dye in

Blevins' example 1 and drugs in Blevins' example 2, and cimetidine and ranitidine in Novotny's example 1).

The separation of small molecule drug and dye analytes is not in the field of applicant's invention, and is not at all pertinent to the separation of nucleic acids. Therefore, neither Blevins nor Novotny qualify as proper § 103 references.

2. The GIBCO and Stratagene references teach away from the claimed invention.

Prior art references must be considered in their entirety, i.e. as a whole, including portions that teach away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). The Court of Appeals for the Federal Circuit further instructed that "references that teach away cannot serve to create a prima facie case of obviousness" (*In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)), and that an "applicant may rebut a prima facie case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect" (*In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997)).

The claims recite methods and devices for extracting nucleic acids from a liquid mixture, using a reversible suction means to draw the mixture through a solid phase in one direction and forcing the mixture over the solid phase in the reverse direction, so that nucleic acids in the mixture bind to the solid phase. The teachings of the GIBCO and Stratagene advertisements are directly opposite to the presently claimed invention. The GIBCO and Stratagene references teach nucleic acid separation methods that involve the passage of a liquid mixture through a nucleic acid binding substrate *in only one direction*. Specifically, the devices in the GIBCO and

Stratagene advertisements use centrifugal force or mechanical pressure, respectively, to pass a nucleic acid containing mixture through a nucleic acid binding solid phase in one direction.

The uni-directional approach described in the GIBCO and Stratagene advertisements are in direct contrast to the bi-directional approach of the claimed invention. Thus, the GIBCO and Stratagene references teach away from the presently claimed invention in this material respect, and as instructed by The Court of Appeals for the Federal Circuit, the references cannot serve as the basis for a proper §103 rejection.

3. There is no motivation to combine the cited references.

Establishing prima facie obviousness requires a showing that each claim element is taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Absent a showing of such motivation and suggestion, prima facie obviousness is not established. See *In re Fine*, 5 USPQ2d at 1598. Further, the prior art cannot be combined to reject claims as prima facie obvious unless one of skill in the art would reasonably expect to achieve the claimed invention based on the combination of the references. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The claims recite methods and devices for extracting nucleic acids from a liquid mixture, using a reversible suction means to draw the mixture through the solid phase in one direction and forcing the mixture over the solid phase in the reverse direction, so that nucleic acids in the mixture bind to the solid phase.

The Office Action acknowledges that Blevins fails to teach nucleic acid separation. See Office Action at paragraph 13. The GIBCO and Stratagene advertisements are offered to cure this defect. The Office Action states that the motivation to combine the Blevins reference with

the GIBCO and Stratagene advertisements is provided by Blevins' suggestion that the disclosed small molecule analyte separation devices can be manipulated so to bind "*desired analytes from a given sample*." See Office Action at paragraph 22. Applicants disagree.

The referenced statement must be considered in context of the Blevins reference as a whole. Blevins provides no clue that the disclosed small molecule analyte separation devices could be adapted and used for nucleic acid separation. In fact, considered as a whole, the Blevins reference suggests that the disclosed small molecule analyte separation devices would not be suitable for nucleic acid purification. While Blevins indicates that desired analytes from a given sample may be extracted using several different types of surface interactions, Blevins states that "the hydrophobic analyte of interest is retained via hydrophobic interactions with the sorbent." See Blevins at page 8, lines 4-5. Blevins discloses the extraction of analytes using hydrophobic and cationic surface interactions and exemplifies only methods and devices for extracting hydrophobic and cationic analytes (See Blevins examples 1 and 2). Further, the methods and devices disclosed in Blevins would not be expected to work to separate nucleic acids, which are not hydrophobic or cationic analytes. Thus, persons of skill in the art of nucleic acid separation would not be motivated to use the methods and devices disclosed in Blevins, much less have any reasonable expectation of success that the methods and devices could be used to separate nucleic acids. Blevins provides neither the motivation nor the reasonable expectation of success required to establish *prima facie* obviousness.

The Office Action also states that Novotny et al., provides motivation required to establish *prima facie* obviousness, since Novotny discloses "a plethora of suitable biological samples." See Office Action at paragraph 22. Applicants disagree.

Novotny exemplifies only the extraction of small molecule analytes (i.e., cimetidine and ranitidine), from mixtures using electrodes to apply a voltage gradient. Novotny provides no clue that such devices could be used or adapted for separation of nucleic acids. Thus, Novotny does not provide the motivation required to establish *prima facie* obviousness of claim 25 (the only claim in the present application that recites the use of electrodes), or any other presently pending claim. In any event, claim 25 has been cancelled and the subject matter of that claim will be pursued in a continuing application.

4. Conclusion

The Blevins and Novotny references teach the separation of small molecule drug and dye analytes. These references are neither analogous to nor pertinent to the claimed invention, which relates to the separation of nucleic acids. The GIBCO and Stratagene advertisements teach nucleic acid separation methods that involve the passage of a liquid mixture through a nucleic acid binding substrate *in only one direction*. These references teach away from the presently claimed invention, which includes the bi-directional use of a reversible suction means to draw a mixture through a solid phase in one direction and forcing the mixture over the solid phase in the reverse direction, so that nucleic acids in the mixture bind to the solid phase. Neither the Blevins or Novotny references provide proper motivation for the adaptation and use of their separation devices for use in separating nucleic acids. Accordingly, none of the cited references, alone or in combination, are sufficient to establish a *prima facie* case of obviousness. Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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